DEC 21 2000

K003264

9. 510(k) Summary of Safety and Effectiveness (in accordance to 21 CFR 807.87(h))

Device Name

Proprietary Device Name: QPS/BPGS/MoCo Processing Applications.

Establishment Name and Registration Number of Submitter

Name:	ELGEMS Ltd.
Registration Number:	9613299
Corresponding Official:	Dan Laor ELGEMS Ltd. P.O. Box 170 Tirat Hacarmel 30200 ISRAEL

Device Classification

Classification Code:	90 KPS
Panel Identification:	Radiology
Classification Name:	Emission Computed Tomography system (Computer)
Common Name:	Nuclear Medicine Software Application
Classification Class:	Class II

Reason for 510(k) Submission

Modification of legally marketed device.

Identification of Equivalent Devices

- ADAC AutoQUANT K980715
- ADAC AutoSPECT K992317
- Siemans E.CAM K992731

Device Description and Intended use

The QPS/BPGS/MoCo Processing Applications are data processing tools to facilitate the analysis of Emission Tomography images (data). These tools are specialized for Cardiac Applications including Quantitative Perfusion SPECT imaging. Blood Pool Gated SPECT imaging, and Motion artifact Correction.

Summary of Studies

Bench and clinical data show that QPS/BPGS/MoCo Processing Applications are fully functional and are operating as intended.

Conclusion

In the opinion of ELGEMS Ltd., QPS/BPGS/MoCo Processing Applications are substantially equivalent in terms of safety and effectiveness to the above mentioned legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 21 2000

Dan Laor
VP for Quality and Regulatory Affairs
Elgems, LTD.
10 Hayozma St., P.O. Box 170
Tirat Hacarmel
Israel

Re: K003264
QPS/BPGS/MoCo Processing Applications for
eNTEGRA Workstation
Dated: October 10, 2000
Received: October 18, 2000
Regulatory class: II
21 CFR 892.1200/Procode: 90 KPS

Dear Mr. Laor:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

510(k) Number (if known): K003264 ~~first submission~~

DEVICE NAME: **QPS/BPGS/MoCo Processing Applications for eNTEGRA Workstation**

INDICATION FOR USE:
QPS is indicated for processing and display of Quantitative Perfusion SPECT imaging.
BPGS is indicated for processing and display of Blood Pool Gated SPECT imaging.
MoCo is indicated for processing and display of Motion artifact Correction.

(Please do not write below this line - continue on another page if needed)

(Concurrence of CDRH, Office of Device Evaluation (ODE))

Prescription Use ✓ OR Over-the-Counter Use _____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K003264